REMARKS

Claims 1 and 2 are pending in this application. Claim 1 has been amended to read "a human infected with human immunodeficiency virus (HIV)"; administering "orally"; "purified, concentrated"; and "wherein said extract weakens HIV activity and inhibits HIV proliferation in said human." No new matter has been added. In view of the foregoing amendments and the following remarks, Applicant believes that the asserted rejections should be withdrawn and that pending claims 1 and 2 are in condition for allowance.

The specification of the instant application has been amended to correct the typographical error 100μ which should have read 100 μl at page 7, paragraph [0045], line 2.

Support for "a human infected with HIV" is found at least at page 5, paragraph [0029], line 3. Support for "orally" administering the extract is found at page 5, paragraph [0029], line 1. Support for "purified, concentrated extract" is found at page 5, paragraph [0028], line 2. In particular, with respect to the term "purified", support is inherent in the preparation method which results in a concentrated, sterilized extract which by definition is "purified". Support for "wherein said extract weakens HIV activity and inhibits HIV proliferation in said human" is found at page 5, paragraph [0030], line 3.

35 U.S.C. § 112 Rejections

Claims 1-5 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Examiner states that claim 1 is vague and indefinite because the preamble is directed to a method for treating viral diseases, whereas the body of the claim is directed to human immunodeficiency virus (HIV) and the subject treated is not identified in the preamble. Additionally, the Examiner asserts that claim 1 is vague and indefinite with respect to the recitation "administering at least one effective dose" and because the mode of administration is not specified.

To overcome this rejection, claim 1 has been amended to recite that the extract is administered orally to a human infected with HIV, wherein said extract weakens HIV activity and inhibits HIV proliferation in said human.

Applicant respectfully points out that it is clear from Amagase, H., "Treatment of hepatitis B patients with *Lentinus edodes* mycelium," *New Trends in Peptic Ulcer and Chronic Hepatitis. Part II. Chronic Hepatitis. Princeton: Exerpta Medica*, 1987, pp. 316-21, which was cited by the Examiner in the Office Action of March 13, 2006 and predates the filing of this invention, *Lentinus edodes* mycelium was administered orally for four months and found to be effective for the treatment of hepatitis B. Amagase does not teach using *Lentinus edodes* mycelium for the treatment of HIV, but does establish that the extract is a recognized, powerful immunomodulator and that orally administering at least one effective dose over a long period of time is within the skill of the art. The invention inheres, therefore, in knowing to give this extract to an HIV patient, not in the already-known details of preparing and administering it long-term.

Furthermore, it is clear from Nagaoka III (JP 58107159, entitled "Preparation of Health Drink"), which also predates the filing date of this invention, that the extract administered according to the claimed invention is a "healthy drink." Thus, it would be clear to one skilled in the art what dosage amount of the extract of the claimed invention to use in an orally consumed healthy drink. Additionally, other dosage issues, such as toxicity, would be understood by one skilled in the art not to be insurmountable – if even relevant - with respect to a healthy drink.

To corroborate this point, Applicant attaches herewith an expert's Declaration dated February 28, 2003, previously submitted and made of record in the parent application 08/519,293. In the Declaration, the declarant attests, in the conclusion, "A highly significant percentage of patients infected with hepatitis B, after daily treatment with the *Lentinus edodes* mycelium extract of the present invention, showed a remarkable improvement in their serum liver enzymes, which was accompanied by Hbe seroconversion from positive to negative, a subjective improvement in symptomatology, and a complete lack of adverse side effects. I also know from my expertise in the area of hepatitis B that hepatitis B patients, left untreated, do not undergo Hbe seroconversion to a highly significant percentage. I therefore conclude that the

results of this patient study emphasize that claim 20 (i.e., the above-described method of making an extract and administering an effective amount to a patient in need of treatment for a viral disease) recites a way of treating viral diseases which accomplishes new and unexpectedly efficacious results, as compared to conventional treatment or no treatment." Therefore, we again see that administering orally at least one effective dose of the extract or healthy drink over a long period of time, produces the desired results. Based on the foregoing, Applicant submits that the specification is more than reasonably enabled for one skilled in the art to practice the present invention as now claimed without undue experimentation.

Thus, the mode of orally administering at least one effective dose is apparent from Amagase and further corroborated by Nagaoka and the Declaration dated February 28, 2003 which establish that one skilled in the art would know the mode of administering an effective dose, notwithstanding in a different context. Therefore, in light of Amagase, Nagaoka, and the Declaration dated February 28, 2003 Applicant respectfully requests, that the grounds for rejection under 35 U.S.C. § 112 for indefiniteness be withdrawn.

Claims 1-5 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner asserts that it cannot be determined for what the treatment is effective against. The Examiner contends that while the specification is enabling for the *in vitro* treatment of viruses such as HIV, it is not enabling for the *in vivo* treatment of all viral diseases.

The present invention as now claimed is directed to a *Lentinus edodes* mycelium extract administered to a human afflicted with HIV to treat the HIV infection. Applicant points out that the specification makes clear that the preparation of the claimed extract has been known prior to the filing of the instant application. Thus, one skilled in the art would already know how to make the extract and to administer it as a healthy drink. Therefore, Applicant submits that one skilled in the art would be able to determine in a reasonable number of tries how to administer the extract to a human afflicted with HIV.

With respect to the Examiner's assertions that *Lentinus edodes* strains are not disclosed in the specification, Applicant points out that all strains of *Lentinus edodes* may be used in the claimed invention, and thus there is no need to specify any particular *Lentinus edodes*

strain. To corroborate this point, Applicant attaches herewith an expert's Declaration dated May 11, 1998, previously submitted and made of record in the parent application 08/519,293. In the Declaration, the declarant attests, in paragraph 7, that "Any strain of the fungus *Lentinus edodes* is suitable for use in practicing the claimed invention. My prior Declaration [dated June 9, 1997] reported results achieved using one strain of *Lentinus edodes*, and that strain is exemplary of all strains of *Lentinus edodes*. The anti-HIV efficacy of an extract produced according to the present invention is essentially unaffected by the strain of *Lentinus edodes*." Based on the foregoing, Applicant submits that the specification is more than reasonably enabled for one skilled in the art to practice the present invention as now claimed without undue experimentation. As the Examiner appreciates, the declaration of an expert is entitled to greater weight than any unsupported allegation to the contrary.

Furthermore, the expert's Declaration dated October 4, 1995, previously submitted and made of record in the parent application 08/519,293, describes the preparation procedure for the extract on pages 2-4. A similar procedure for preparation of the extract is described in the expert's Declaration dated June 9, 1997, also previously submitted and made of record in the parent application 08/519,293, is described on page 2.

Therefore, it is clear from the expert's Declarations from 1995, 1997, and 1998 that all strains of *Lentinus edodes* may be used in the claimed invention and suitable methods for preparation of the extract. Therefore, rejection under 35 U.S.C. § 112 for lack of enablement should be withdrawn.

In view of the foregoing remarks, it is respectfully submitted that pending claims 1 and 2 in the present application comply with the requirements of Section 112 and are in condition for allowance. Accordingly, reconsideration and withdrawal of the rejection and an early Notice of Allowance are respectfully requested.

Respectfully submitted,

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